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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/654,743	× 09/01/2000	Robert G. Korneluk	07891/003005	7148
7	7590 01/06/2003			
Kristina Bieker-Brady, Ph.D. Clark & Elbing LLP 176 Federal Street			EXAMINER	
			KAUSHAL, SUMESH	
Boston, MA 02110			ART UNIT	PAPER NUMBER
			1636	\overline{C}
			DATE MAILED: 01/06/2003	6

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/654,743	KORNELUK ET AL.				
Office Action Summary	Examiner	Art Unit				
	Sumesh Kaushal Ph.D.	1636				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1) Responsive to communication(s) filed on <u>24 September 2002</u> .						
2a) This action is FINAL . 2b) Th	This action is FINAL . 2b) This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims						
4) Claim(s) <u>1,3-14, 30-32 and 48-78</u> is/are pend	ing in the application					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) 1,3-14, 30-32 and 48-78 are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
 a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal f	(PTO-413) Paper No(s) Patent Application (PTO-152)				

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DETAILED ACTION

The Preliminary amendment filed on 09/01/00 has been acknowledged.

Claims 2, 15-29 and 33-47 are canceled.

Claims 1, 3-14 and 30-32 and 48-78 are pending and are examined in this office action.

▶ If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (http://www.uspto.gov) and <u>A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.</u>

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-4, 8-12, 30, 5, 52, 54, 62, 67, 74, 75, drawn to a nucleic acid encoding a human XIAP polypeptide, classified in class 536, subclass 23.1.
- II. Claims 1, 3-4, 8-12, 30, 7, 55, 57, 66, 68, 71, 76, drawn to a nucleic acid encoding a <a href="https://maintage.numan.num
- III. Claims 1, 3-4, 8-12, 30, 6, 58, 60, 64, 69, 72, 77, drawn to a nucleic acid encoding a <u>human HIAP2</u> polypeptide, classified in class 536, subclass 23.1.
- IV. Claims 1, 3-4, 8-12, 30, 5, 52, 53, 61, 70, 73, 78, drawn to a nucleic acid encoding a mouse XIAP polypeptide, classified in class 536, subclass 23.1.
- V. Claims 1, 3-4, 8-12, 30, 7, 13, 31, 48, 55, 56, 65, drawn to a nucleic acid encoding a mouse HIAP1 polypeptide, classified in class 536, subclass 23.1.

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- VI. Claims 1, 3-4, 8-12, 30, 6, 14, 32, 49, 58, 59, 63, drawn to a nucleic acid encoding a mouse HIAP2 polypeptide, classified in class 536, subclass 23.1.
- VII. Claims 50, drawn to a nucleic acid encoding a <u>BIR domain</u> selected from SEQ ID NO: 45, 46, 47, 49, 50, 51, 53, 54, 55, 57, 58, 59, 61, 62, 63, 65, 66 and 67 polypeptide, classified in class 536, subclass 23.1.
- VIII. Claims 51, drawn to a nucleic acid encoding a <u>RXF domain</u> selected from SEQ ID NO: 48, 52, 56, 60, 64 and 68, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I, II, III and IV, V, VI are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of Group I, IV (XIAP), II, V (HIAP1) and III, VI (HIAP2) are structurally distinct nucleic acid sequences, which encodes functionally distinct polypeptides. For example, the polypeptides encoded by each nucleic acid sequence would interact with structurally distinct components involved in apoptotic pathway. In addition the human and mouse IAP analogs are distinct since they work in structurally and functionally distinct cellular environment having different specificities. In addition, the nucleic acid of XIAP, HIAP1 and HIAP2 are distinct from the invention of Groups VII (BIR) and VIII (RZF), since a polynucleotide bearing BIR or RZF domain may not encode a polypeptide that have a functional activity like an IAP polypeptide. Thus these inventions are distinct and are of separate uses.

In order to be perfectly clear, the following Inventions within the particular Groups are NOT species elections. These are independent and distinct Inventions for the reasons given above and a further election of a single Invention from the elected Group is required.

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With regard to Groups VII the independent and distinct Inventions are as follows:

- i. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 45
- ii. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 46.
- iii. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 47.
- iv. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 49.
- v. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 50.
- vi. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 53.
- vii. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 54.
- viii. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 55.
- ix. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 57.
- x. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 58.
- xi. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 59.
- xii. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 61.
- xiii. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 62.
- xiv. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 63.
- xv. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 65.
- xvi. Nucleic acid encoding a BIR domain selected from SEQ ID NO: 66.
- xvii. Nucleic acid encoding a BIR domain selected from SEO ID NO: 67.

With regard to Groups VIII the independent and distinct Inventions are as follows:

- i. Nucleic acid encoding a RZF domain selected from SEQ ID NO: 48.
- ii. Nucleic acid encoding a RZF domain selected from SEO ID NO: 52.
- iii. Nucleic acid encoding a RZF domain selected from SEQ ID NO: 56.
- iv. Nucleic acid encoding a RZF domain selected from SEQ ID NO: 60.
- v. Nucleic acid encoding a RZF domain selected from SEQ ID NO: 64.
- vi. Nucleic acid encoding a RZF domain selected from SEQ ID NO: 68.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed Invention.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches for each Group would be divergent from each other Group, so restriction for examination purposes as indicated is proper

With regard to the different Inventions, the burden of search exists because a different search is required for all the inventions for Groups VII and VIII. For example, in order to properly search the nucleic acid of Group VII and VIII each SEQ ID NO: need to be searched in the computer database maintained by the STIC and will also require individualized searching of the related activity in databases like Medline, Biosis, Scisearch and Caplus etc. The inventions as claimed in here have different modes of operation, functions and effects, which need to be separately reviewed. Since the review of this information would be different for each invention it would be burdensome.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal

Patent examiner

JEFFREY FREDMAN PRIMARY EXAMINER